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June 11, 2019

VIA FACSIMILE

The Honorable Joel Schneider
United States Magistrate Judge
District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, NJ 08101

**Re: In re Valsartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-JS**

Dear Judge Schneider:

This letter is to provide Defendants' position with respect to the topics on the agreed agenda for the teleconference with Your Honor on June 12.

1. Discovery Confidentiality Order

The parties have prepared a revised draft of the Discovery Confidentiality Order based on the Court's decisions and comments during the May 29th, 2019 Case Management Conference. Defendants prepared and circulated the revised draft on Tuesday, June 11th, 2019. Defendants intended to use the transcript of the May 29th CMC, which would have been useful to confirm rulings and finalize language on several points in the draft, but since the transcript has not been prepared as of the submission of this letter, Defendants circulated a draft to facilitate entry of the Discovery Confidentiality Order by the Court's stated goal of June 12th, 2019. The parties will continue to confer in an effort to finalize the draft and will be ready to address any outstanding issues with the Court at this week's discovery teleconference on June 12th, 2019.

Duane Morris

The Honorable Joel Schneider
June 11, 2019
Page 2

2. Core Discovery

Those defendants subject to the Core Discovery Order dated April 29, 2019 (Dkt. No. 88) will begin their productions on June 17, 2019 with Drug Master Files, Abbreviated New Drug Applications, and recall communications with the FDA, and will supplement that production on a rolling basis through July 19, 2018, with the production of Form 483's, Establishment Inspection Reports, CGMP inspection reports, and warning letters, if any, in accordance with the Core Discovery Order.¹

The core discovery documents will not be produced with all of the technicalities required under the ESI Protocol, such as all of the metadata required under that protocol. However, in accord with the Court's guidance at the May 29 Status Conference, Defendants intend to produce the core discovery files as Bates-stamped PDFs with basic categories of metadata to allow Plaintiffs to understand how those documents are maintained in the ordinary course of business.

3. Master Complaints

Defendants look forward to receiving the Plaintiffs' Master Complaints on June 17.

4. Short Form Complaints

Plaintiffs circulated a draft Short Form Complaint to defense counsel, and Defendants are currently reviewing and preparing to provide feedback on Plaintiffs' draft. Defendants will provide preliminary comments on this draft to Plaintiffs by Friday, June 14, and anticipate that further comments may follow once Defendants are able to review Plaintiffs' Master Complaints, which

¹ Items relating to API manufacturing are not available to Aurobindo Pharma USA, Inc. or AuroLife Pharma LLC. Those documents belong to Aurobindo Pharma Ltd. located in Hyderabad, India. Aurobindo Pharma Ltd. has not been served in any action and is not represented by counsel. It is possible that counsel for Aurobindo Pharma USA, Inc. and AuroLife Pharma LLC may not represent Aurobindo Pharma Ltd. in this litigation.

Hetero USA does not have these categories of core discovery documents. Items relating to API manufacturing are not in Hetero USA's possession. Those documents belong to Hetero Labs Limited (Hetero Labs) located in Hyderabad, India. Upon information and belief, Hetero Labs has not been served in any action and is not represented by counsel. Counsel for Hetero USA does not presently represent Hetero Labs and has no indication it will represent Hetero Labs in this litigation. Nonetheless, we are advised that Hetero USA is continuing discussions with Hetero Labs to explore the production of core discovery documents which are not in Hetero USA's possession.

Duane Morris

The Honorable Joel Schneider
June 11, 2019
Page 3

are to be filed on June 17. Regardless, Defendants anticipate the parties will be in position to finalize the Short Form Complaint at or before the June 26 Status Conference.

5. Insurance Information

Defendants required to produce insurance information have produced their insurance policies. To the extent they are required to be produced, Defendants are in the process of ascertaining whether reservation of rights letters have been issued, and, if so, collecting those for production.

6. Streamlined Service Protocol

The parties have agreed to a streamlined service protocol, and intend to submit the agreed protocol to the Court as a proposed Case Management Order this week.

7. Plaintiff Fact Sheets

Defendants have formed a dedicated subcommittee and are finalizing their draft Plaintiff Fact Sheet which will be circulated to Plaintiffs' counsel no later than Friday, June 14th, 2019. Defendants intend to adopt the structure and substance of the *Benicar* Plaintiff Fact Sheet wherever appropriate, though modified to fit this litigation, and will endeavor to work with Plaintiffs to have a draft ready for the Court's consideration by the June 26th, 2019 Status Conference.

8. ESI Protocol

The parties have finalized an ESI Protocol, consistent with the Court's rulings, and have filed it with the Court as [Proposed] Case Management Order No. 8.

9. Stipulation for Dismissal of Peripheral and Minor Defendants

Defendants are preparing a response to Plaintiffs' latest redline, and anticipate having that circulated to Plaintiffs by Friday, June 14.

10. Document Repositories

Defendants have selected an eDiscovery vendor to house and maintain materials produced in connection with this MDL. Defendants are now working with the vendor to open the repository.

11. Coordination of State Cases

Defendants have drafted a proposed Joint Coordination Order and circulated this order to Plaintiffs for review. However, the parties have not yet had the opportunity to meet and confer on this issue.

Duane Morris

The Honorable Joel Schneider
June 11, 2019
Page 4

As discussed in greater detail in the Agenda for May 29, 2019 Case Management Conference, *see* ECF 107 at 9–10, there are currently multiple Valsartan-related actions pending outside the MDL. A brief update on the six actions identified in the Agenda for May 29 follows:

- *Runo v. Princeton Pharmaceutical Inc.*, No. MID-L-00856-19 (N.J. Super.) and *Orlowsky v. Solco Healthcare U.S., LLC*, No. MID-L-0002554-19 (N.J. Super.):

The court has entered a stipulation in *Runo* to coordinate proceedings with the MDL. The parties have requested the same stipulation in *Orlowsky*, but the court has not yet responded.

- *Shanov v. Walgreens Co.*, No. 2018-CG-15272 (Cook Co. Cir. Ct., Illinois):

There are no further developments in this case.

- *Collins v. Princeton Pharmaceutical Inc.*, No. 3:19-cv-00415 (S.D. Cal.) and *Collins v. Aurobindo Pharma USA, Inc.*, No. 3:19-cv-0688 (S.D. Cal.):

These actions are still pending before the JPML. The parties in *Collins v. Aurobindo* have completed briefing on Plaintiff's opposition to transfer to the MDL, but the JPML has not yet ruled. Briefing on Plaintiff's opposition to transfer of *Collins v. Princeton* is ongoing and will not be complete until June 24.

In addition to the six actions identified in the Agenda for May 29, another has been filed in New Jersey Superior Court, Middlesex County: *Robertson v. Princeton*, No. MID-L-004228-19 (N.J. Super.). *Robertson* is not removable and has not yet been assigned to a judge. Plaintiffs' counsel in *Robertson* is a member of Plaintiffs' leadership in this MDL and also represents the plaintiffs in *Runo* and *Orlowsky*.

12. Inclusion of Losartan and Irbesartan

At the May 29 Status Conference, Plaintiffs voiced their intent to petition the Joint Panel on Multidistrict Litigation to include losartan and irbesartan in this litigation. However, no such petition has been filed, nor have additional losartan and irbesartan cases been filed since the May 29 Status Conference.

Defendants look forward to discussing these issues with the Court during the June 12, 2019 telephone conference.

Duane Morris

The Honorable Joel Schneider
June 11, 2019
Page 5

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

SAG

cc: Adam Slater, Esq. (*via email, for distribution to Plaintiffs' Counsel*)
Jessica Priselac, Esq. (*via email, for distribution to Defendants' Counsel*)
Lori G. Cohen, Esq. (*via email*)
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